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TECHNOLOGY CENTER R3700

Serial Number: 09/896,542 Application Filed: 06/29/2001

Applicant: Pepi Dakov

Application Title: Connectors for Hollow Anatomical Structures and Methods of Use

Preliminary Class/Sub-Class: 606/153

Examiner: Nerbun, Peter P

GAU: 3765

Mailed: February 16, 2002

Rego Park, NY

Information Disclosure Statement

Assistant Commissioner for Patents and Trademarks Washington, DC 20231

Sir:

Attached is a completed Form PTO-1449 and copies of the references cited thereon. Following are the comments on these references:

Angelchik describes an apparatus and method for effecting anastomotic procedures in US Patent 4,352,358. The described apparatus consists of two rings connected with an elastic membrane. One of the rings is placed inserted through an opening into a hollow organ. In expanded position, the two rings are larger than the opening of the hollow organ. This tensions the elastic membrane and sealingly engages it with the opening of the hollow organ.

Kaster describes an anastomotic fitting for coronary bypass graft surgery in US Patent 4,368,736. It includes a flanged tube and multiple anchors (by which the fitting is attached to the side organ), and a graft fixation collar (for attaching the fitting to the end of the bypass graft). The flange of the tube is inserted into the opening of the organ and fixed by the anchors (pins) that pierce the wall from the outside.

Klawitter describes a suture ring for attaching heart valves in US Patent 4,535,483. The heart valve is coupled to the ring by deformable protrusions of the ring that engage with the valve and to secure the fabric. The ring is attached to the surrounding tissues by manual suturing of the fabric.

Chareire describes a quick connect system for connecting a blood vessel to a cardiac prosthesis in US Patent 4,650,486. The system comprises to annular connectors. The surgeon first "fixes by sutures 5, the connectors 6 the cut ends of the ends of the arteries 3a and the atria 7" and then the connectors are coupled by a quick connect system.

Davis describes an apparatus and method for repairing and preventing para-stomal hernias in US Patent 4,854,316. The device consists of a tubular mesh and two sheet-like meshes attached perpendicularly to the tubular mesh. An intestine is introduces into the tubular mesh and attached with stitches. The two sheet-like meshes are affixed internally to the abdominal wall and beneath the skin respectively with manual sutures.

Kaster describes a side-to-end vascular anastomotic staple apparatus and method in US Patents 5,234,447; 5,366,462; and 5,403,333. The "staple" consists of a rigid annular base member (a rigid ring) and a plurality of oppositely facing first and second engaging members. A vessel end is placed through the staple and cuffed over the first engaging members so they pierce the cuffed vessel. The first engaging members are then deformed. After that the cuffed vessel end (mounted on the deformed first engaging members) is introduced into the side opening, and the second engaging members are deformed to press the sidewall from outside.

Chen describes an anastomotic device in US Patent 5,336,233 that compares of two rings. One of the rings is positioned inside and the other on the outside. Two hollow organs are compressed between the two rigid rings that are locked by pins piercing the two organs.

Owen describes a tubular surgical implant having a locking ring and flange in US Patent 5,456,714. The implant constitutes a tube with a deformable flange on one end and a locking ring. The flange is introduced into a side opening of a hollow organ. Multiple spikes extend from the flange and pierce the wall of the organ. The spikes fit and lock into a plurality of holes of the locking ring that slides down axially. In this way, the organ is compressed between the flange and the ring.

Schenck describes an anastomosis device and method for anastomosing blood vessels in US Patent 5,486,187. The device consists of a rigid ring with several needle-like projections and multiple staple-like fasteners. The end of one of the first vessel is cuffed over the ring and impaled over the projections. The end of the second vessel is drawn

over the ring and the cuffed first vessel. Then, the fasteners are applied and closed to keep the vessel in a sealed position around the ring.

Sharkey describes a passive fixation anastomosis method and device in US Patent 5,540,701. The passive fixation device constitutes a coil that is inserted into the two organs and then the coil is expanded to press the organs from inside.

Chang describes an anastomosing device in US Patent 5,752,966. It consists of a flexible member having a first end and a second end, which can be closed in a loop. By penetrating protrusions, it joins the overlapping walls of two organs.

Spence describes an anastomotic device for joining blood vessels in US Patent 5,868,763 and means and methods for performing anastomosis in US Patent 6,190,397. The device consists of two malleable cuffs that are attached to the two organs and coupled together. Each cuff consists of a flexible body made of woven fabric cuffs. A stiffening framework, which is made of deformable material that can be deformed from a first configuration to a second configuration, is integrated into the flexible body.

Tozzi describes apparatus and method for improved sutureless anastomosis in US Patent 5,916,226. The apparatus includes to annular amiprotheses that hold close to each other (but not in contact) the ends of a pair of ducts and means for connecting the two emiprotheses. The apparatus is for end-to-end anastomosis only and does not have a one-body embodiment.

Berg and Bachinski describe tubular graft connectors and methods in US Patent 5,972,017; and in continuing US Patens 6,152,945 and 6,293,965. Among other things they show a connector that has an annular component circumferentially compressible to fit an axial end portion of a conduit and inwardly projecting prongs. Resilient fingers may extend radially outward to retain the annular structure in an aperture of a side wall of body conduit. For end-to-end connectors it may include a second annular component similar to the first one.

Goldstein describes medical grafting methods and apparatus in US Patent 5,976,178 and in US Patent 6,302,905 for installing tubular bypass grafts intralumenally in which both ends of the grafts site are approached separately.

Bachinski describes oblique-angle connectors in US Patent 6,001,124. The connectors include two elongated members interconnected by series of struts. The connector is attached to the side vessel by hooks. The struts are bendable and when released the two elongated members move axially to each other, which angels the attached connector.

Berg describes a T-shaped medical graft connector in US Patent 6,068,654. The device is a two-piece connector for end-to-side anastomosis. It includes a tubular band that is attached to the end, retention loops affixed to the tubular band, and a tubular anchor structure that is placed axially within the side vessel.

Swanson describes anastomosis apparatus in US Patents 6,113,612 and 6,309,416. The anastomosis apparatus includes radially spaced first and second portions and radially outwardly deflectable members of first and second portions respectively the overlapping side and end walls.

Sullivan describes medical grafting methods and apparatus in US Patent 6,120,432 and in Patent 6,186,942 for installing tubular bypass grafts intralumenally in which both ends of the grafts site do not require to be approached separately.

Peterson describes a graft connector and method of making and installing the same in US Patent 6,152,937. The connector accomplishes end-to-side anastomosis. It consists of a frame ring and four pluralities of fingers that in deployed position keep the overlapped side and end walls compressed.

Gifford describes devices and methods for performing vascular anastomoses in US Patent 6,171,321. The described devices perform end-to-side anastomoses. The devices require the end of the graft to be everted when anastomosed to the side of the vessel.

Solem describes an anastomotic fitting for end-to-side anastomosis in US Patent 6,179,848. The fitting includes a sleeve with multiple ribs flanged outwardly by a balloon. The flanged ribs ever the end of the vessel. The side and end walls are compressed between the flanged ribs and a locking ring on the outside.

Yencho describes a sutureless closure for connecting a bypass graft to a target vessel in a US Patent No. 6,179,849. The device includes a frame that holds the graft in everted position and approximates it to the external side surface of the vessel.

Bolduc describes a system for performing vascular anastomoses in US Patent 6,193,734. The system performs end-to-side anastomosis. The end vessels is pierced by tissue securing members and everted. In deployed configuration the securing members compress the side and end walls.

Levin describes an anastomosis device and methods in a US Patent No. 6,241,743. The device is used for end-to-side anastomosis. The flanged end inside the side opening is compressed between a fastener on the outside and radial extensions on the inside.

None of the above cited references describes a connector with an inner fluidproof surface formed by the union of two annular rigid bodies (seamlessly consolidated or coupled) that surround the abutted cut edges of wall openings (end or sidewall openings) of approximated first and second hollow anatomical structures, and first and second holding means capable of keeping the first and second hollow structures adjoined to the fluidproof surface, as this was recited in independent claims 1, 5, and 12 and hence in their dependent claims 2 to 4, 6 to 11, and 13 to 19.

Also, none of the above references describes a method for joining two hollow anatomical structures with the help of the described novel union connector, as this was recited in independent claims 20 and 22, and hence in their dependent claims 21 and 23.

Very respectfully,

Peri Durov

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ENC: PTO-1449 and thirty three references